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Fax Cover Sheet

Date: 21 Aug 2002

To: Mi Kim	**From:** Jessica H. Roark
Application/Control Number: 09/484,577	**Art Unit:** 1644
Fax No.: (858) 678-5099	**Phone No.:** (703) 605-1209
Voice No.: (858) 678-5070	**Return Fax No.:** (703) 746-5174
Re: 09/484,577 Gordon et al.	**CC:**

☐ **Urgent** ☒ **For Review** ☐ **For Comment** ☐ **For Reply** ☐ **Per Your Request**

Comments:
Please consider the attached proposed Examiner's amendment. The proposed amendment obviates the rejections of record, and should place the case in condition for allowance IF no art is identified when the search is updated.

I have spoken with several senior examiners and one of the Practice Specialists for TC1600, and none of us have been able to identify in the specification sufficient written description for claims to PCR primer pairs. It is suggested that Applicant file a CIP to pursue this subject matter.

The kit and method claims are presented as multiply dependent claims, but certainly could be presented as

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Jessica

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Number of pages 4 **including this page**

Proposed Examiner's Amendment to 09/484,577.

PLEASE NOTE: A NEW SEARCH WILL BE REQUIRED FOR THE SPECIFIC NUCLEIC ACID PROBES!

In the Specification:

1. On page 22 at line 26, the hyperlink has been removed by deleting the phrase "accessible as http://blocks.fhcrc.org/codehop.html, and is".

In the Claims:

2. Claims 1-4, 9-14, 16, 28-29, 43 and 45-50 will be cancelled.

3. The following new claims will be added:

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51. An isolated or recombinant nucleic acid consisting of SEQ ID NO:3, or its complement.

52. An isolated or recombinant nucleic acid encoding the polypeptide consisting of SEQ ID NO:4, or its complement.

53. An expression vector comprising the isolated or recombinant nucleic acid of claim 51 or claim 52 operably linked to a promoter in the sense orientation.

54. A transformed cell comprising the isolated or recombinant nucleic acid of claim 51 or claim 52.

55. A transformed cell comprising the expression vector of claim 53.

56. A heterologous nucleic acid comprising the isolated or recombinant nucleic acid of claim 51 or claim 52.

57. A nucleic acid probe that is 10 to 20 to 30 or more contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

58. A nucleic acid probe that is 10 to 50 contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

59. A nucleic acid probe that is greater than 50 contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

60. A nucleic acid probe that is between about 15 and about 200 contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

61. A nucleic acid probe that is between about 25 and about 100 contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

62. A nucleic acid probe that is between about 35 and about 75 contiguous nucleotides of the nucleic acid consisting of SEQ ID NO:3.

63. A kit for detecting the presence of nucleic acid sequences associated with giant cell arteritis comprising the nucleic acid probe of any one of claim 57, claim 58, claim 59, claim 60, claim 61 or claim 62, and instructional material.

64. A method for diagnosing giant cell arteritis comprising:

(a) providing a nucleic acid sample from an arteritis lesion biopsy,

(b) transferring the nucleic acid sample to a membrane,

(b) contacting the membrane with a nucleic acid probe of any one of claim 57, claim 58, claim 59, claim 60, claim 61 or claim 62, and

(c) detecting whether the nucleic acid probe hybridizes to the nucleic acid sample on the membrane;

wherein specific hybridization is diagnostic for giant cell arteritis. --

REASONS FOR ALLOWANCE

4. The following is an Examiner's Statement of Reasons for Allowance:

The specification discloses that a fusion polypeptide formed by joining the nucleic acid consisting of SEQ ID NO:3 (GCA1b) to GST was specifically bound by sera from GCA+ patients but not bound by sera from GCA- patients (pages 80-84 and Figure 3). The Gordon Declaration under 37 CFR 1.132, filed 3/20/02, provides evidence that SEQ ID NO:3 is a nucleic acid that is present in GCA+ biopsy samples but not detectable in GCA- biopsy samples. Therefore, the nucleic acid consisting of SEQ ID NO:3 and fragments thereof have diagnostic utility for GCA, as does a nucleic acid encoding a protein consisting of SEQ ID NO:4.

Therefore, the Examiner's Amendment set forth supra, in conjunction with Applicant's amendments filed 3/20/02 and 7/24/02 (Paper Nos. 16 and 17) and the Gordon Declaration under 37 CFR 1.132, filed 3/20/02, have obviated the previous rejections of record in Paper No. 14.

Support for the nucleic acid probes may be found in the specification at least on pages 68-70, with support for the probe lengths being found in the specification on pages 2-3, bridging paragraph; page 20 at lines 16-19; and pages 68-69, bridging paragraph.

Support for a "heterologous nucleic acid" may be found in the specification at least on page 10, lines 21-30.

Support for kits comprising instructional material may be found in the specification at least on page 78, lines 1-11.

Support for the method steps of the diagnostic assay may be found in the specification at least on pages 68-70 in view of pages 18-20.

Accordingly, the instant claims are deemed allowable.